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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/260,533	12/09/2011	Roland Opfer	2009P00061WOUS	7666

38107 7590 01/25/2018

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
01/25/2018	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROLAND OPFER, LILLA BOROCZKY, INGWER CURT CARLSEN, PRADYUMNA DUTTA, STEFFEN RENISCH, JOERG SABCZYNSKI, and PAOLA KARINA TULIPANO

Appeal 2016-004625[1]
Application 13/260,533[2]
Technology Center 3600

Before NINA L. MEDLOCK, KENNETH G. SCHOPFER, and MATTHEW S. MEYERS, *Administrative Patent Judges*.

MEDLOCK, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] Our decision references Appellants' Appeal Brief ("App. Br.," filed September 16, 2015) and Reply Brief ("Reply Br.," filed March 30, 2016), and the Examiner's Answer ("Ans.," mailed February 10, 2016) and Final Office Action ("Final Act.," mailed April 24, 2015).

[2] Appellants identify Koninklijke Philips Electronics NV as the real party in interest. App. Br. 1.

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134(a) from the Examiner's final rejection of claims 1–9, 11–13, 15, 16, 19, and 21–25. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

CLAIMED INVENTION

Appellants' claimed invention "relates to the medical arts, clinical arts, medical imaging arts, and related arts" (Spec. 1, ll. 2–3).

Claims 1, 11, and 24 are the independent claims on appeal. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A non-transitory storage medium storing instructions executable by at least one computer having a display to define an oncology monitoring system including:
>
> an imaging controller configured to operate an imaging system to acquire medical images of a subject;
>
> an oncology monitoring module configured to perform oncological monitoring operations that operate on medical images of a subject to quantitatively analyze a cancerous tumor; and
>
> a clinical guideline support module configured to:
>
> (i) display, on the display of the computer, a graphical flow diagram of a chemotherapy, brachytherapy, or radiation therapy protocol comprising a plurality of successive chemotherapy, brachytherapy, or radiation therapy sessions, and interface a user to navigate the displayed graphical flow diagram, wherein the graphical flow diagram comprises blocks including imaging assessment blocks representing oncological monitoring operations performed on medical images of the subject by the oncology monitoring module and therapeutic operation blocks representing therapeutic chemotherapy, brachytherapy, or radiation therapy operations in which chemotherapy, brachytherapy, or radiation therapy

treatment is delivered to the subject, the therapeutic operation blocks not being performed by the oncology· monitoring: module., and

(ii) annotate the graphical flow diagram with subject-specific information, including annotating scan parameters used in acquiring a medical image of the subject to an imaging assessment block representing an oncological monitoring operation medical image of the subject by the oncology monitoring module and annotating an imaging assessment block with a quantitative result of the oncological monitoring operation represented by the imaging assessment block and annotating a therapeutic operation block with subject-specific information pertaining to administration to the subject of the therapeutic operation represented by the therapeutic operation block;

wherein the oncology monitoring system is configured to monitor a chemotherapy, brachytherapy, or radiation therapy protocol performed on a subject having a cancerous tumor by operations including:

annotating a graphical flow diagram of the chemotherapy, brachytherapy, or radiation therapy protocol performed on the subject having the cancerous tumor with subject-specific information;

using the clinical guideline support module, interfacing a user to navigate the graphical flow diagram with the annotated subject-specific information to identify the next imaging assessment block to be performed on the subject and annotating the identified imaging assessment block with scan parameters;

using the imaging controller, acquiring one or more medical images of the subject using the imaging controller with the scan parameters annotated to the selected assessment block;

using the oncology monitoring module and the acquired medical images, performing the oncological monitoring operation represented by the identified imaging assessment block to generate a quantitative analysis of the cancerous tumor; and

> using the clinical guideline support module, annotating the identified imaging assessment block with the quantitative analysis of the cancerous tumor.

REJECTIONS

Claims 1–9, 11–13, 15, 16, 19, and 21–25 are rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter.

Claims 1–8, 11–13, 15, 16, 21, and 23–25 are rejected under 35 U.S.C. § 103(a) as unpatentable over Sano et al. (US 2004/0254465 A1, pub. Dec. 16, 2004) (hereinafter "Sano"), Meissner et al. (US 2009/0287066 A1, pub. Nov. 19, 2009) (hereinafter "Meissner"), and Reiner (US 2007/0106633 A1, pub. May 10, 2007).

Claims 9 and 19 are rejected under 35 U.S.C. § 103(a) as unpatentable over Sano, Meissner, Reiner, and Beckett et al. (US 2007/0127793 A1, pub. June 7, 2007) (hereinafter "Beckett").

Claim 22 is rejected under 35 U.S.C. § 103(a) as unpatentable over Sano, Meissner, Reiner, and Becker et al. (US 6,904,161 B1, iss. June 7, 2005).

ANALYSIS

Non-Statutory Subject Matter

Under 35 U.S.C. § 101, an invention is patent-eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. The Supreme Court, however, has long interpreted § 101 to include an implicit exception: "[l]aws of nature, natural phenomena, and abstract ideas" are not patentable. *See, e.g., Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014).

The Supreme Court, in *Alice*, reiterated the two-step framework previously set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), "for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice Corp.*, 134 S. Ct. at 2355. The first step in that analysis is to "determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* If the claims are not directed to a patent-ineligible concept, e.g., an abstract idea, the inquiry ends. Otherwise, the inquiry proceeds to the second step where the elements of the claims are considered "individually and 'as an ordered combination"' to determine whether there are additional elements that "'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 566 U.S. at 78).

The Court acknowledged in *Mayo*, that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71. Therefore, the Federal Circuit has instructed that claims are to be considered in their entirety to determine "whether their character as a whole is directed to excluded subject matter." *McRO, Inc. v. Bandai Namco Games Am., Inc.*, 837 F.3d 1299, 1312 (Fed. Cir. 2016) (quoting *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015)).

Here, independent claim 1 is directed to "[a] non-transitory storage medium storing instructions executable by at least one computer . . . to define an oncology monitoring system," and recites that the system includes, *inter alia*, an oncology monitoring module configured to monitor a therapy protocol performed on a subject having a cancerous tumor by operations

including "acquiring one or more medical images of the subject using the imaging controller with the scan parameters annotated to the selected assessment block" and "using the oncology monitoring module and the acquired medical images, performing the oncological monitoring operation . . . to generate a quantitative analysis of the cancerous tumor." Claim 11 is similarly directed to an oncology monitoring system, and recites that the system comprises a computer configured to "perform oncological monitoring operations on images of a subject to analyze a cancerous tumor of the subject." Independent claim 24 is directed to a method for monitoring a chemotherapy, brachytherapy, or radiation therapy protocol performed on a subject having a cancerous tumor, and recites that the method comprises, *inter alia*, "performing an oncological monitoring operation . . . on medical images acquired using the scan parameters annotated to the identified imaging assessment block to generate a quantitative analysis of the cancerous tumor."

In rejecting the pending claims under § 101, the Examiner finds that the claims are directed to the abstract idea of planning treatment and monitoring a tumor, i.e., "displaying a graphical flow diagram, annotating a graphic flow diagram, navigating the graphical flow diagram, acquiring images of a tumor, performing oncological monitoring, and annotating quantitative analysis of the tumor"; and that the claims do not include additional elements sufficient to amount to significantly more than the judicial exception because the additional elements or combination of elements other than the abstract idea amount to "no more than: mere instructions to implement the idea on a computer, and recitation of generic computer structure that serves to perform generic computer functions that

are well-understood, routine, and conventional activities previously known to the pertinent industry" (Final Act. 2–3).

We find that the Examiner's characterization of the claims as directed to the abstract idea of planning treatment and monitoring a tumor does not properly account for the step of "using the imaging controller, acquiring one or more medical images of the subject using the imaging controller with the scan parameters annotated to the selected assessment block," as recited in independent claim 1, and similarly recited in independent claims 11 and 24, and therefore, does not reflect the character of the claims as a whole.

Therefore, we do not sustain the rejection of claims 1–9, 11–13, 15, 16, 19, and 21–25 under 35 U.S.C. § 101.

Obviousness

Independent Claim 1 and Dependent Claims 2–9

In rejecting claim 1 under 35 U.S.C. § 103(a), the Examiner cites Sano as disclosing substantially all of the claim limitations (Final Act. 4–10). But the Examiner acknowledges that Sano does not explicitly teach a "graphical flow diagram of a chemotherapy, brachytherapy, or radiation therapy protocol comprising a plurality of successive chemotherapy, brachytherapy, or radiation therapy sessions," as recited in claim 1 (*id.* at 6). And the Examiner cites Meissner to cure the deficiency of Sano (*id.*). More particularly, the Examiner cites Figure 2 of Meissner as disclosing the claimed graphical flow diagram and blocks 48, 50, 52, 54, and 60 in Figure 2 as disclosing a plurality of successive therapy sessions (*id.*) The Examiner explains that the term "session" is interpreted "consistent with a definition provided in *The American Heritage Dictionary of the English Language*" to mean "'a period of time devoted to a specific activity'" (*id.*

at 33), and that each of blocks 48, 50, 52, 54, and 60, as disclosed in Meissner, "would independently meet the requirements of a period of time devoted to a therapy, consistent with the definition of 'session'" (*id.*)

Meissner is directed to a method for minimally invasive medical intervention, and discloses a workflow process, with reference to Figure 2, for performing a minimally invasive intervention on the patient to treat, remove, or otherwise address a detected tumor (Meissner ¶¶ 18–21). As shown in Figure 2, the intervention includes a plurality of steps, as shown, for example, in blocks 48, 50, 52, 54, and 60, and Meissner discloses that execution of the intervention steps and confirmation of the effectiveness of the intervention are performed without moving the patient from the intervention suite and possibly without moving the patient from his/her position on the examination and treatment table (*id.* ¶ 22).

Appellants argue that the Examiner construed the term "session" overly broadly, and, thus, erred in characterizing Figure 2 of Meissner, and in particular, blocks 48, 50, 52, 54, and 60, as disclosing "a plurality of successive chemotherapy, brachytherapy, or radiation therapy sessions," as called for in claim 1 (App. Br. 15–18). Appellants maintain that Meissner's Figure 2 depicts a single intervention procedure workflow, i.e., a single therapy protocol, and that, rather than constituting a plurality of successive therapy sessions, blocks 48, 50, 52, 54, and 60, are the steps of a single therapy session.

Appellants point to page 1, lines 12–14 of the Specification as defining a "chemotherapy, brachytherapy, or radiation therapy session" to mean "a chemotherapy, brachytherapy, or radiation therapy treatment followed by a recovery period of typically a few days to a few weeks" (*id.*

at 16).[3] Yet, we find nothing in the cited portion of the Specification that defines a chemotherapy, brachytherapy, or radiation therapy session to include a recovery period. Instead, we agree with the Examiner that a person of ordinary skill in the art would reasonably understand from the Specification, including, in particular, the language at page 1, lines 8–14, that the recovery period is a separate period of time rather than a part of the treatment session (Ans. 36). As such, we agree with the Examiner that blocks 48, 50, 52, 54, and 60 in Figure 2 of blocks 48, 50, 52, 54, and 60 in Figure 2 Meissner constitute "a plurality of successive therapy sessions," as called for in claim 1 under a broad, but reasonable, interpretation.

Appellants note that the Examiner cites Reiner as disclosing an electronic workflow method that includes recording information specific to a particular tumor (App. Br. 19). And Appellants argue that although "this may be a quantitative result of an oncological monitoring operation performed by imaging assessment, . . . there is no mention [in Reiner] of annotating this result to any block of any graphical flow diagram" (*id.*).

The difficulty with that argument is that claim 1 is rejected as obvious over the combination of Sano, Meissner, and Reiner, not over Reiner alone. Although it may be appropriate in circumstances where a single reference is cited as disclosing a particular claim limitation, to present arguments aimed

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[3] The Specification, at page 1, lines 8–14, reads:

A series of therapies are then performed, which may include chemotherapy, brachytherapy, radiation therapy, or the like. Typically, these therapies are performed over an extended period of time and take the form of chemotherapy, brachytherapy, or radiation therapy sessions. At each session, the patient enters the hospital on an in-patient or out-patient basis, and undergoes a therapy treatment session. A recovery period follows typically between a few days and a few weeks.

at rebutting the presence of the claimed feature in that single reference, such arguments are not persuasive where the claim limitation is found in the teachings of a combination of references. *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.").

We are not persuaded on the present record that the Examiner erred in rejecting independent claim 1 under 35 U.S.C. § 103(a). Therefore, we sustain the Examiner's rejection. We also sustain the Examiner's rejection of dependent claims 2–9, which are not argued separately.

Independent Claims 11 and 24 and Dependent Claims 12, 13, 15, 16, 19, 21–23, and 25

Appellants' arguments with respect to independent claims 11 and 24 (App. Br. 21–27) are substantially identical to Appellants' arguments with respect to claim 1, and are similarly unpersuasive. Therefore, we sustain the Examiner's rejection of claims 11 and 24 under 35 U.S.C. § 103(a). We also sustain the Examiner's rejection of dependent claims 12, 13, 15, 16, 19, 21–23, and 25, which are not argued separately.

Dependent Claims 9, 19, and 22

Claim 9 depends from independent claim 1, and claims 19 and 22 depend from independent claim 11. Appellants do not present any arguments to support the patentability of these dependent claims except to assert that the additional cited references do not cure the alleged deficiencies in the combination of Sano, Meissner, and Reiner with respect to claims 1 and 11 (App. Br. 27–28).

We are not persuaded, for the reasons set forth above, that the Examiner erred in rejecting independent claims 1 and 11 under 35 U.S.C. § 103(a). Therefore, we also sustain the Examiner's rejections of dependent claims 9, 19, and 22.

DECISION

The Examiner's rejection of claims 1, 2, 5–9, 12–16, and 19–21 under 35 U.S.C. § 101 is reversed.

The Examiner's rejections of claims 1, 2, 5–9, 12–16, and 19–21 under 35 U.S.C. § 103(a) are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED